

31 1. (Amended) A pharmaceutical composition for oral administration of fenofibrate comprising:

a) a therapeutically effective amount of fenofibrate; and

b) a solubilizer comprising a vitamin E substance,

wherein the fenofibrate is at least about 50% solubilized in the composition.

32 3. (Amended) The pharmaceutical composition of claim 1, wherein said vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

B3 2. (Amended) The pharmaceutical composition of claim 54, wherein said solubilizer is a trialkyl citrate.

B4 5. (Amended) The pharmaceutical composition of claim 54, wherein said solubilizer is a lactone.

35 B7 C1 10. (Amended) The pharmaceutical composition of claim 54, wherein said solubilizer is a nitrogen-containing solvent.

B6 37. (Amended) The pharmaceutical composition of claim 1, in a liquid form.

38. (Amended) The pharmaceutical composition of claim 1, in a semi-liquid form.

B7 40. (Amended) The pharmaceutical composition of claim 1, wherein the fenofibrate is at least 75% solubilized in the composition.

41. (Amended) A pharmaceutical dosage form comprising the pharmaceutical composition of claim 1.

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B7  
CONT 42. (Amended) The pharmaceutical dosage form of claim 54, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

43. (Amended) The pharmaceutical dosage form of claim 54, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

B8 46. (Amended) The pharmaceutical composition of claim 1, wherein the fenofibrate is completely solubilized in said composition.

B9 50. (Amended) A pharmaceutical composition for administration of a hydrophobic drug comprising:

- (a) a therapeutically effective amount of a hydrophobic drug; and
- (b) a vitamin E substance,

wherein the hydrophobic drug is present in an amount of from about 0.1 to 30 % w/w of the composition and is at least about 50% solubilized in the composition, the vitamin E substance is present in an amount of from about 1 to 99 % w/w of said composition, and the hydrophobic drug is selected from the group consisting of hydrophobic drugs that have not been micronized and hydrophobic drugs that have been micronized in the absence of a solid surfactant.

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C37 51. (Amended) A method for treating a patient suffering from a fenofibrate-responsive condition, disease or disorder, comprising administering to the patient a therapeutically effective amount of the pharmaceutical composition of any one of claims 1, 54 or 66.

Also add the following new claims 52-94:

B10 --52. The pharmaceutical composition of claim 40, wherein the fenofibrate is completely solubilized in the composition.

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*Cont*  
*B10*  
53. The pharmaceutical dosage form of claim 41, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

*sub*  
*C4*  
54. A pharmaceutical composition for oral administration of fenofibrate, comprising:  
a) a therapeutically effective amount of fenofibrate; and  
b) an effective solubilizing amount of a solubilizer selected from the group consisting of a trialkyl citrate, a lactone, a nitrogen-containing solvent, and combinations thereof.

*11*  
55. The pharmaceutical composition of claim *54*, wherein the fenofibrate is at least 50% solubilized in the composition.

*12*  
56. The pharmaceutical composition of claim *55*, wherein the fenofibrate is at least 75% solubilized in the composition.

*13*  
57. The pharmaceutical composition of claim *56*, wherein the fenofibrate is completely solubilized in the composition.

*14*  
58. The pharmaceutical composition of claim *54*, in a liquid form.

*sub*  
*C5*  
59. The pharmaceutical composition of claim 54, in a semi-liquid form.

*16*  
60. A pharmaceutical dosage form comprising the pharmaceutical composition of claim *54*.

*sub*  
*C6*  
61. The pharmaceutical dosage form of claim 60, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

62. The pharmaceutical dosage form of claim 60, wherein the unit dosage is from about 40 mg to about 250 mg.

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63. The pharmaceutical dosage form of claim 62, wherein the unit dosage is from about 67 mg to about 200 mg.

64. The pharmaceutical dosage form of claim 60, in capsule form.

65. The pharmaceutical dosage form of claim 60, in the form of a drink.

66. A pharmaceutical composition for oral administration of fenofibrate comprising:  
a) a therapeutically effective amount of a hydrophobic drug selected from the group consisting of fenofibrate that has not been micronized and fenofibrate that has been micronized in the absence of a solid surfactant; and  
b) a solubilizer comprising a vitamin E substance, a trialkyl citrate, a lactone, a nitrogen-containing solvent or combination thereof; and  
c) an optional solid surfactant.

67. The pharmaceutical composition of claim 66, wherein the fenofibrate has not been micronized.

68. The pharmaceutical composition of claim 66, wherein the fenofibrate has been micronized in the absence of a solid surfactant.

69. The pharmaceutical composition of claim 66, wherein the solubilizer is a vitamin E substance.

70. The pharmaceutical composition of claim 69, wherein the vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

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C7  
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B10

71. The pharmaceutical composition of claim 70, wherein the vitamin E substance is selected from the group consisting of alpha tocopherol, alpha tocopheryl acetate, alpha tocopheryl acid succinate, alpha tocopherol polyethylene glycol 1000 succinate and mixtures thereof.

72. The pharmaceutical composition of claim 71, wherein the solubilizer is a trialkyl citrate.

73. The pharmaceutical composition of claim 72, wherein the trialkyl citrate is selected from the group consisting of triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate and mixtures thereof.

74. The pharmaceutical composition of claim 73, wherein the trialkyl citrate is triethyl citrate.

75. The pharmaceutical composition of claim 66, wherein the solubilizer is a lactone.

76. The pharmaceutical composition of claim 75, wherein the lactone is selected from the group consisting of  $\epsilon$ -caprolactone and isomers thereof,  $\delta$ -valerolactone and isomers thereof and  $\beta$ -butyrolactone and isomers thereof and mixtures thereof.

77. The pharmaceutical composition of claim 66, wherein the solubilizer is a nitrogen-containing solvent.

78. The pharmaceutical composition of claim 77, wherein said nitrogen-containing solvent is selected from the group consisting of dimethylformamide, dimethylacetamide, N-alkylpyrrolidone, N-hydroxyalkylpyrrolidone, N-alkylpiperidone, N-alkylcaprolactam and mixtures thereof.

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79. The pharmaceutical composition of claim 78, wherein the solubilizer is selected from the group consisting of N-methyl 2-pyrrolidone, N-ethyl 2-pyrrolidone and mixtures thereof.

80. The pharmaceutical composition of claim 66, in a liquid form.

81. The pharmaceutical composition of claim 66, in a semi-liquid form.

82. The pharmaceutical composition of claim 66, wherein the fenofibrate is at least 50% solubilized in the composition.

83. The pharmaceutical composition of claim 82, wherein the fenofibrate is at least 75% solubilized in the composition.

84. The pharmaceutical composition of claim 83, wherein the fenofibrate is completely solubilized in the composition.

85. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 66.

86. The pharmaceutical dosage form of claim 85, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

87. The pharmaceutical dosage form of claim 86, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

88. The pharmaceutical dosage form of claim 87, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

89. The pharmaceutical dosage form of claim 85, in capsule form.

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